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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,152	07/23/2003	David B. Agus	67789-19	1369

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EXAMINER
COOK, REBECCA

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/625,152	AGUS, DAVID B.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 July 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 10,21 and 29-56 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9,11-20,22-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

### **DETAILED ACTION**

Applicant's election with traverse of R5 when it is C=O and the prostate cancer when it is androgen-independent in the reply filed on July 11, 2005 is acknowledged. The traversal is on the ground(s) that a search of the two groups would not constitute an undue burden on the Examiner. This is not found persuasive because it would constitute an undue burden on the Examiner to search the full scope of the invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 11-20, 22-28, 35-43, 45-54 and 56 read on the elected invention are examined. Applicant recites that claims 10, 21, 29-34, 44 and 55 do not read on the elected invention and are withdrawn. Additionally, claims 35-56 read on non-elected androgen-dependent prostate cancer and are withdrawn from examination.

It is noted that the claims and specification are directed only to the treatment of prostate cancer.

#### ***Claim Objections***

Claims 1-9, 12-20, 23-25 and 27-28 are objected to as containing non-elected subject matter.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-9, 11-20 and 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The intent of the method is not clear since the method is to treating a mammal and not to treating androgen-independent prostate cancer. Amending the claims to

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recite "A method of treating androgen-independent prostate cancer in a mammal in need thereof..." will overcome this rejection.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "androgen-independent" in claims 1, 12, 23 and 26 is used by the claim to mean "hormone refractory prostate cancer" (see Applicant's definition on page 2, lines 6-7), while the accepted meaning of "androgen-independent prostate cancer" (AIPC) implies a potential for patients to respond to a secondary hormonal measure, while the term "hormone-resistant prostate cancer" (HRPC) includes patients who do not respond to various hormone treatments or who have progressed following these treatments and would not be expected to respond to another. In the Crawford "D" classification, both would be included in the "D3 category, with D3S and D3I indicating hormonally sensitive and hormonally resistant cases, respectively. (Diaz et al, Cancer Control, Nov/Dec 2004, p 365, right column). The term is indefinite because the specification does not clearly redefine the term.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-20 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 652 004 in view of Diaz and Raghaw et al.

'004 (page 4, lines 1-37) discloses that the instant compound is useful for treating resistant neoplasms, including prostate cancer. '004 does not recite androgen-independent prostate cancer. However, Diaz' et al definition of AIPC implies a potential for patients to respond to a secondary hormonal measure. Therefore, it would be obvious to one of ordinary skill in the art to use the compound of '004 to yield the instant method, because '004 discloses that the instant compound is useful for treating resistant neoplasms. This would include those for whom a primary measure was no longer effective.

Dependent claims differ over the references in reciting dosages and route of administration. Other claims recite that an estrogen lowering drug is further administered. However, once a method of use is known it is within the skill of the artisan to determine the optimum dosage and route of administration.

Furthermore, Raghaw et al (abstract) discloses that toremifene is an antiestrogen that is useful in treating prostate cancer. In the absence of unexpected results no unobviousness is seen in using two compounds together, each of which is known to be useful to treat the same condition.

Note that Clinical Trials discloses that toremifene was used to treat prostate cancer in 2001.

Claims 1-9, 11-20 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubauer et al 1995 and Raghaw et al.

Neubauer 1995 (page 221, left column) discloses that the instant compound is a physiological antagonist of androgen and is used to treat prostate cancer. The claims differ over Neubauer in reciting androgen-independent cancer. However, Neubauer (abstract) discloses that the instant compound is also effective in the treatment of hormone-insensitive human prostate cancer. It would be obvious to use the compound of Neubauer to yield the instant method because Neubauer discloses that the instant compound is also effective in the treatment of hormone-insensitive human prostate cancer.

Dependent claims differ over the references in reciting dosages and route of administration. Other claims recite that an estrogen lowering drug is further administered. However, once a method of use is known it is within the skill of the artisan to determine the optimum dosage and route of administration. Furthermore, Raghaw et al (abstract) discloses that toremifene is an antiestrogen that is useful in treating prostate cancer. In the absence of unexpected results no unobviousness is seen in using two compounds together, each of which is known to be useful to treat the same condition.

Note that Clinical Trials discloses that toremifene was used to treat prostate cancer in 2001.

***Double Patenting***

Applicant is requested to identify any cases in which there may be obviousness-type double patenting.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Primary Examiner  
Art Unit 1614

August 22, 2005